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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,507	11/07/2003	Jacques Degelaen	Neogen 4.1-48	8535

21036 7590 05/15/2008

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 05/15/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10702507	11/7/2003	DEGELAEN ET AL.	Neogen 4.1-48

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EXAMINER	
Bao-Thuy L.. Nguyen	
ART UNIT	**PAPER**
1641	20071205

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Commissioner for Patents

A supplemental Examiner's Answer is attached. The #10 has been inserted beside Response to Arguments and heading number 11, Related Proceedings Appendix, along with text has been added.

Any questions concerning this communication or earlier communication should be directed to Bao-Thuy Nguyen at (571) 272-0824.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit: 1641

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/702,507
Filing Date: November 07, 2003
Appellant(s): DEGELAEN ET AL.

Ian C. McLeod
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 19 September 2007 appealing from the Office action mailed 06 March 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,319,466	Markovsky et al	11-2001
6,074,869	Pall et al	6-2000

Joris et al., FEMS Microbiology Letters. Vol. 70. No. 1. 15 June 1990. Pages 107-113.

EP 0 093 613 Litman et al. (09 November 1983).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24, 26-32 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markovsky et al (US 6,319,466) in view of Joris (*FEMS Microbiology Letters*. Vol. 70. No. 1. 15 June 1990. Pages 107-113) and Litman et al (EP 0 093 613).

Markovsky discloses a device comprising a labeled receptor positioned within or proximate to a membrane. The membrane comprises a test zone having an analyte conjugate immobilized thereto to bind unbound receptor to form a first analyte conjugate receptor complex. The membrane further comprising a control zone including a binder immobilized thereto. See column 1, lines 52-67. Markovsky teaches that the receptor may bind a family of analytes which have similar structural binding sites. Markovsky also discloses a sample absorbing and a mobile-phase support zone acting as a filter for somatic cells. See column 9, lines 7-14. The mobile-phase support zone is preferably Porex® pad or Porex® Lateral Flow Media (a rigid pore structure made from high density polyethylene). See column 10, lines 25-29. The device is configured to detect analytes such as beta lactams antibiotics in milk samples. See column 5, lines 11-20. The entire device is provided in a blister package including a removable seal strip at one end for application of the sample. See column 4, lines 8-20. Markovsky teaches that competitive assays for beta-lactams in milk sample can be done in 2 to 15 minutes. See column 3, lines 26-32. Markovsky teaches that test kits for detecting beta-lactams in biological fluids are well known in the art. See column 1.

Markovsky differs from the invention in failing to teach receptors obtained from *Bacillus lichenformis* as the labeled reagent. Markovsky also fail to teach a reference that is independent of the analyte.

Joris, however, discloses BLAR and BLAR-CTD involved in β-lactamase inducibility in *Bacillus lichenformis*.

And, Litman discloses a method and device for detecting an analyte comprising a measurement surface and a calibration surface binding to a reagent independent from the analyte. See page 4, lines 24-37.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the receptors taught by Joris in the device of Markovsky because Markovsky teaches that their device can be modified for the detection of a variety of analytes, including those disclosed in claim 32, using appropriate reagents. See column 13, lines 23-39. Markovsky teaches that most of the elements for each test are the same except the chemistries of the mobile phase, test zone and control zone, which are tailored to the specific analyte detection. Since Joris discloses that receptors of as BLAR and BLAR-CTD are readily available are and well known in the art as having β-lactamase activity, a skilled artisan would have had a reasonable expectation of success in using receptors BlaR or BlaR-CTD to detect beta-lactams antibiotics such as penicillin as taught by Markovsky.

Even though Markovsky does not specifically teaches that the mobile-phase support zone (i.e. purification membrane) retains leukocytes, Markovsky teaches that this zone is capable of filtering somatic cells, therefore, a skilled artisan would have had

a reasonable expectation of success that such a membrane is capable of retaining leukocytes.

The use of an independent reference or calibration reagent is well known in the art and a skill artisan would have been motivated to use the calibration method and reagents taught by Litman in the device of Markovsky because Markovsky teaches a control comprising a broad spectrum antibody that is captured at the reference zone regardless of the presence or absence of an analyte in a sample and Litman teaches that it is advantageous to use a reagent that is independent from the analyte to provide a calibration or reference signal such that a standard for evaluation of the analyte at the detection zone can be obtained.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markovsky in view of Joris and Litman as applied to claim 24 above, and further in view of Pall et al (US 6,074,869).

See the discussion of Markovsky, Joris and Litman above. These references differ from the instant invention in failing to specifically disclose the pore size of the purification membrane.

Pall, however, teaches membranes for filtering biological samples, including leukocytes and milk sample. See column 6, lines 32-62. Pall teaches that their

membrane is a non-woven web (i.e. polyethylene) having an average pore size of 3 to 8μm. See column 8, lines 54-60.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the purification membrane taught by Pall in the device of Markovsky as modified by Joris because such a membrane is well known in the art and provides the advantage of a substantially uniform porous medium that can separate large somatic cells from a biological sample.

(10) Response to Arguments

Appellant's arguments have been fully considered but they are not persuasive. Appellant argues that the prior art rejection is based upon the premise that it would be "obvious to try" to adapt the BlaR or BlaR-CTD proteins of Joris to the lateral flow assay of Markovsky even though Joris does not suggest any assays at all.

This argument is not persuasive. Markovsky teaches a device specifically for detecting beta lactam antibiotics in milk samples such as claimed. Markovsky teaches the detection of a variety of analytes including penicillin, ampicillin, ceftiofur, etc (column 13, lines 25-40) using reagents tailored specifically to the analyte. As such, it is entirely within the skills of the ordinary artisan to choose a receptor that is specific for the analyte, and since Joris teaches that receptors to penicillin, BlaR and BlaR-CTD, are readily available and are well known in the art as having β-lactamase activity, it would,

have been obvious for one of ordinary skill in the art to use these receptors in the device of Markovsky to detect penicillin in milk samples.

Appellant argues that in a complex lateral flow assay as claimed, there would be no assurance that the BlaR or Blar-CTD receptors would function since the complex with the antibiotic is subjected to lateral flow and different proteins have different flow characteristics, therefore, one skilled in the art could not predict that the BlaR or BlaR-CTD receptors could function in this manner.

This argument is not persuasive. Lateral flow assays are well known in the art and Markovsky recognizes the need to test the mobility of sample such as milk to optimize reaction times and uniformity. Markovsky discloses that high pore size membranes (15 to 140 μm) are used to allow flow of viscous samples like milk or serum (column 11, lines 64-67). Therefore, there is clear guidance for an ordinary artisan to test the mobility of the reagents in an assay to optimize reaction times and uniformity as taught by Markovsky. Furthermore, Markovsky teaches the detection of beta-lactams antibiotic in milk samples just as those in the instant claims. Markovsky teaches the use of beta lactam receptors purified from bacteria, and since BlaR and BlaR-CTD are also beta-lactam receptors purified from bacteria, these receptors would be expected to be similar to those disclosed by Markovsky and would also be expected to have similar characteristics, therefore, the simple substitution of the beta-lactam receptors taught by Markovsky with the beta-lactam receptors of Joris would be expected to yield

predictable results. There is every expectation that the beta-lactam receptors taught by Joris would be able to flow through the device of Markovsky since these receptors are similar.

Appellant argues that there is no suggestion that BlaR or BlaR-CTD bound with the antibiotics would pass through the web described by Pall. One skilled in the art would have no basis for suggesting that the Pall fibrous web could be used in the claimed lateral flow assay kit for dairy products.

This argument is not persuasive. Pall teaches membranes for filtering biological samples including leukocytes. See column 6, lines 32-62. Pall specifically teaches polyethylene membrane having pore size of 3 to 8 μm. See column 8, lines 54-60 and column 18, lines 17-27. Since this membrane is similar to that which is taught by Markovsky (i.e. polyethylene membrane), and since the membrane of Markovsky has been shown to be capable of supporting the flow of BlaR or BlaR-CTD bound to antibiotic as argued above, one of ordinary skill in the art would have had a reasonable expectation of success in using the membrane taught by Pall in the device of Markovsky for the advantage of a substantially uniform porous medium that can separate large somatic cells from a biological sample. Furthermore, the membrane taught by Pall has the same pore size as that of the instant claims; therefore, this membrane would inherently possess the same characteristics as the claimed membrane. If the claimed

membrane with its 8 μm pore size can support the flow of BlaR or BlaR-CTD bound to antibiotic, than the membrane of Pall with its 8μm pore size can also support the same. For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

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PRIMARY EXAMINER
1/17/08

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